UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

THIS DOCUMENT RELATES TO:
The County of Summit, Ohio, et al. *v. Purdue Pharma L.P.*, et al.
Case No. 18-op-45090

The County of Cuyahoga, Ohio, et al. *v. Purdue Pharma L.P.*, et al.
Case No. 1:18-op-45004

Track One-B

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

JOINT STATUS REPORT FOR DECEMBER 4, 2019
TRACK ONE-B CASE MANAGEMENT CONFERENCE

Pursuant to the Court's November 26, 2019 Order, the parties provide the following joint status report in advance of the Track One-B Case Management Conference on December 4, 2019.

Track One-B adds dispensing claims to the distribution claims pursued in Track One. On December 2, 2019, counsel for the parties in Track One-B met and conferred regarding Track One-B discovery. The parties discussed (1) their respective approaches to the case, (2) prioritizing certain discovery requests as a means of focusing the remainder of discovery, (3) the temporal scope of discovery and whether it should differ depending on the nature of the discovery; and (4) the nature and volume of deposition discovery.

Plaintiffs submitted to the Pharmacy Defendants a list of 10 priority requests including items such as sales/dispensing data and policies/guidelines for dispensing and anti-diversion procedures, i.e. documents and materials that are central to plaintiffs' dispensing claims. A copy

of the initial disclosure request is attached as Exhibit A. Likewise, the Pharmacy Defendants have submitted to Plaintiffs priority requests that include identification of the prescriptions that Plaintiffs contend should not have been filled. The Pharmacy Defendants' priority requests are Attached as Exhibit B.

The parties did not reach resolution on any issue but have agreed that it would be helpful to continue discussions on the key issues pertaining to the scope of discovery. In the meantime, the parties propose that at the December 4, 2019 case management conference, they address the Court on the issues presented by Track One-B and outlined below.

A. Certain Positions of the Pharmacy Defendants

Because dispensing claims have yet to be litigated in this MDL, discovery related to those claims is entirely new and entirely different from the previous discovery related to distribution claims. When the Pharmacy Defendants were sued in their capacity as registered distributors, the claims were based on a regulation related to "suspicious order monitoring" that does not apply to pharmacies, i.e., 21 C.F.R. § 1301.74(b).[1] Discovery focused on systems put in place by registered distributors for monitoring, reporting, and shipping wholesale orders placed by pharmacies. The focus was on wholesale orders by pharmacies, not prescriptions for patients.

In contrast, the regulation related to dispensing—21 CFR § 1306.04(a)—imposes a "corresponding responsibility" on pharmacists—not distributors—not to "knowingly fill" "a prescription issued not in the usual course of professional treatment." Compliance with that regulation involves the exercise of professional judgment by a licensed pharmacist when presented with an individual prescription for a patient and does not involve "monitoring" of "suspicious" wholesale orders or prescriptions at an aggregate or corporate level. As a result,

[1] By its terms, 21 C.F.R. S 1301.74(b) applies only to "non-practitioner" registrants, and pharmacies are "practitioners." *See* 21 U.S.C. S 802(21).

discovery on Plaintiffs' new pharmacy claims will be different from the discovery previously taken. It will focus on different conduct, different standards, different facilities and different witnesses. Indeed, there is no overlap between the witnesses who conducted suspicious order monitoring and the witnesses who filled prescriptions.

The Pharmacy Defendants understand that Plaintiffs seek to establish violations of the standard of care through the use of data and will seek to limit discovery accordingly. But because, among other things, the standard of care applicable to dispensers requires the real-time exercise of judgment by a licensed professional, based on the patient presenting the prescription, the doctor who wrote it, and other available information, aggregate proof is not sufficient to prove a violation. *In the Matter of Holiday CVS, L.L.C.*, Dkt. No. 12-37 and 12-38 (U.S. Dept. Of Justice, Drug Enf't Admin.) (April 13, 2012) (proof of "aggregate numbers … shed no light on the extent to which the registrants here executed their corresponding responsibility and thus would provide no relevant evidence").

In any event, the exercise of a pharmacist's professional judgment trumps any so-called "red flags" plaintiffs might claim should have prevented a given prescription. Moreover, even if the Court were to permit the use of aggregate proof, and Plaintiffs were to rely on it exclusively, Pharmacy Defendants are certainly entitled to defend the claims by discovering the facts and circumstances surrounding the prescriptions at issue. In addition to new depositions of witnesses from DEA, Ohio Board of Pharmacy, the Ohio Board of Medicine, hospitals, and Ohio schools of pharmacy, this will include depositions of doctors and possibly patients. To deny the Pharmacy Defendants this dispensing-related discovery, in the face of allegations that the Pharmacy Defendants improperly dispensed medications pursuant to prescriptions written by these doctors and presented by these patients, would be to violate not only the Federal Rules but

also Due Process. These are the witnesses who can testify that the prescriptions Plaintiffs contest were appropriate and necessary. The discovery is both relevant and central to Plaintiffs' dispensing claims.

B. Certain Positions of Plaintiffs

Plaintiffs submit that the Chain Pharmacy Defendants' as dispensers conduct is a similar manner as their status as Distributors and is governed by the "Controlled Substances Act ("CSA" or the "Act") and its implementing regulations create restrictions on the distribution of controlled substances. See 21 U.S.C. §§ 801-971 (2006); 21 C.F.R. §§ 1300-1321 (2009). The Act authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market. See 21 U.S.C. §§ 821, 822. Any entity that seeks to become involved in the production or chain of distributing controlled substances must first register with the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1301.11. Under the DEA's regulations, registered pharmacies must "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. §1301.71(a)." *Holiday CVS, L.L.C. v. Holder* et al, No. 1:2012cv00191 - Document 47 (D.D.C. 2012)

Simply put, plaintiffs submit that the conduct in dispensing opioids is governed by the same laws, regulations, and duties as their distribution of opioids. Just as in their distribution of opioids, the Controlled Substances Act and its implementing regulation, 21 CFR 1304.74 require Pharmacy Defendants to maintain effective controls to prevent diversion and to detect, report, and reject suspicious orders. But, as dispensers, Pharmacy Defendants have additional information and data, which provides an additional visibility into red flags or patterns of potential diversion, and a "corresponding responsibility" to prevent diversion. That duty is owed

not only by the individual pharmacist but also by the pharmacy at a corporate level. As the DEA has noted, pharmacies are not only a link in the opioid supply chain, but the last line of defense against diversion.

Plaintiffs maintain that these claims can be proven through aggregate proof and the individualized depositions of doctors or patients is improper and irrelevant, Plaintiffs submit that Pharmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular according to article submitted by CVS and published in the New England Journal of Medicine, Mitch Betses, R.Ph., and Troyen Brennan, M.D., M.P.H., *Abusive Prescribing of Controlled Substances - A Pharmacy View*, N. ENGL. J. MED. 369;11, Sept. 12., 2013, at 989-991.(This document was produced by CVS in discovery and assigned bates no. CVS-MDLT1-000000418 and is attached hereto as Exhibit C). Under the CSA, pharmacies have a responsibility not to fill prescriptions if there is reason to believe the prescriptions were not "issued for a legitimate medical purpose…in the usual course of [] professional practice." 21 C.F.R. § 1306.04(a). *See also Holiday CVS, LLC*, Fed. Reg. Vol. 77, No. 198 (2012). The "red flags" described in DEA guidance and related caselaw must be resolved before a prescription can be legally dispensed.[2] Red flags include multiple patients at the same address or with the same last name, piecemeal filling of prescriptions, "pattern prescribing" of substantially identical prescriptions from the same doctor, prescribing certain drug combinations (*e.g.* "drug cocktails"), prescriptions for high quantities or doses, temporal proximity of prescriptions, lack of geographic proximity between the patient at the doctor or pharmacy, immediate release prescriptions for pain patients, and frequency of refills ("Red Flags").[3] Thus, these improper

[2] *See e.g. Holiday CVS, LLC*, Fed. Reg. Vol. 77, No. 198 (2012)
[3] *See Holiday CVS, LLC*, Fed. Reg. Vol. 77, No. 198 (2012); *Holiday CVS, LLC v. Holder*, 839 F. Supp. 2d 145 (D.C. 2012) (mooted due to CVS's failure to timely petition for review); *Oak Hill Hometown Pharmacy v. Dhillon*, No. 2:19-cv-

prescriptions can be, should have been, and sometimes were identified through the aggregate analysis of data that reveals patterns of red flags, and not an individualized, prescription-by-prescription review.

As noted above, Plaintiffs submit that Chain Pharmacies have a particular "advantage" identifying Red Flags under the CSA because Chain Pharmacies can use "aggregated information on all prescriptions filled at the chain" in order to examine patterns of opioids and other "high-risk drugs" and target "inappropriate prescribing." *Id*. at 990. For example, CVS uses its chainwide dispensing data to identify "high risk prescribers" by "benchmarking" prescription data based on "several parameters," including "volume of prescriptions for high-risk drugs," "the proportion of the prescriber's prescriptions that were for such [high-risk] drugs, as compared with the volume and proportion for others in the same specialty and region," cash payment, ages of patients, and the prescriber's ratio of "prescriptions for noncontrolled substances with prescriptions for controlled substances." ("CVS Test"). *Id*. This "[a]nalysis of aggregated data" from chain pharmacies can "target patterns of abuse," in the face of "the growing use of controlled substances and resulting illnesses and deaths." *Id.* Accordingly, "innovative use of transparent data is only prudent." *Id.*

The analysis of the chain pharmacies' dispensing data, including the type of data utilized by the CVS Test, in conjunction with other evidence will reveal that the chain pharmacies routinely dispensed prescriptions without resolving red flags and thus failed to meet their corresponding responsibility under the CSA. Plaintiffs are prepared to affirm that they will not assert, either in expert opinions or factual presentations at trial, that any specific prescriptions

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00716, 2019 WL 5606926 (S.D. W.V. Oct. 30, 2019); *Jones Total Health Care Pharmacy, LLC v. DEA*, 881 F.3d 823 (2018); *Pharmacy Doctors Enterprises, Inc. v. DEA*, No. 18-11168, 2019 WL 4565481 (11th Cir. Sept. 20, 2019); *East Main Street Pharmacy, DEA Affirmance of Suspension Order*, Fed. Reg. Vol. 75, No. 207 (2010); U.S. Centers for Disease Control, CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, 65 Morb. And Mort. Wkly Rep. (March 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf

dispensed by the Pharmacy Defendants were unauthorized, medically unnecessary, ineffective, or harmful or that the filling of any specific prescriptions caused or led to harm for which Plaintiffs seek to recover, and instead will rely, at trial and in expert opinions, solely on a theory of aggregate proof.

CONCLUSION

The parties look forward to addressing the Court on these issues at tomorrow's case management conference and to continuing to confer with one another on an appropriate discovery plan.

Date: December 3, 2019 Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 3rd day of December, 2019, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF Systems.

s/Peter H. Weinberger
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